solution inside the sample supply unit, wherein the biosensor to which the sample solution is supplied is separate from the control means.

REMARKS

Claims 11-18 are pending in the application. Claims 2-10 have been cancelled, without prejudice. Support for each of the new claims 12-16 is found at least in claims 2-6 as originally filed. Support for new claims 11, 17, and 18 is found at least in the specification in Figures 4 and 5, as originally filed; at page 20, lines 17-19 and page 7, lines 9-10 (support for the language "pH range adequate for activity").

The specification has been amended by deletion of the section entitled "ABSTRACT OF THE DISCLOSURE" and replacement of a new section entitled "ABSTRACT OF THE DISCLOSURE" in accordance with Rule 1.121(b)(2). A marked up version of the section showing the changes made is attached hereto.

I. Objection to the Specification.

At page 2 of Paper No. 8, the Examiner has objected to the specification because of the use of the word "means" in the Abstract. The Abstract has been amended to eliminate use of the term "means". However, applicants point out that the term "means" is used appropriately and definitely in the claims and specification to identify a portion of the sample solution treating instrument.

Accordingly, as the Examiner's objection is no longer applicable, the applicants respectfully request that it be reconsidered and withdrawn.

II. Rejection Under 35 U.S.C. § 112, First Paragraph.

Also at page 2 of Paper No. 8, the Examiner has rejected claim 10 under 35 U.S.C. § 112, first paragraph, asserting that such claim is not enabled by the specification. Although claim 10 has been cancelled, the applicants traverse this rejection, should it be applied to any of the new claims.

A claim is fully enabled by the specification if a person of ordinary skill in the art could make or use the invention based upon the disclosure in the specification coupled with information known in the art without undue experimentation. *See*, M.P.E.P. 2164.01, *citing U.S. v. Telectronics, Inc.*, 8 U.S.P.Q. 2d 1217, 1223 (Fed. Cir. 1988). Claim 10 is fully enabled, for sample supply units of sponge and of elastic materials other than sponge. The specification

articulates that the sample supply unit may be made of any elastic material "capable of retaining the sample solution inside," and a person of ordinary skill would easily recognize what materials could be encompassed within this definition. *See, e.g.*, page 13 at lines 20-23.

Accordingly, it is respectfully requested that the Examiner reconsider and withdraw the enablement rejection with respect to claim 10 and not apply such rejection to the new claims.

III. Rejection Under 35 U.S.C. § 112, Second Paragraph.

The Examiner has rejected claims 5, 7, and 10 under 35 U.S.C. § 112, second paragraph. The Examiner contends that these claims are indefinite for use of the term "proper." Claims 5, 7, and 10 have been cancelled. Claims 5 and 10 have been rewritten as claims 15 and 18 respectively. Neither of new claims 15 and 18 uses the term "proper". Accordingly, as this rejection is no longer applicable, it is respectfully requested that the Examiner reconsider and withdraw it, and not apply it to the new claims.

IV. Rejection Under 35 U.S.C. § 102(b).

The Examiner has rejected each of claims 2-8 as anticipated under 35 U.S.C. § 102(b) based upon one or more of the following references: U.S. Patent No. 5,262,305 of Heller *et al.* ("Heller"); U.S. Patent No. 5,124,253 of Foulds *et al.* ("Foulds"); U.S. Patent No. 4,431,507 of Nankai *et al.*, ("Nankai"); U.S. Patent No. 5,271,819 of Bockowski ("Bockowski"); and U.S. Patent No. 4,279,618 of Barden ("Barden"). Although claims 2-8 have been cancelled, the applicants respectfully traverse these rejections, should they be applied to the new claims, for the reasons given below.

The invention of this application is a sample solution treating instrument that allows for the simple adjustment of a sample solution, such as saki moromi or a nutritional drink, to place it in a condition suitable for more rapid and more accurate analysis by an external biosensor. The sample solution is treated in the control means of the sample solution treating instrument, which is equipped to place the sample solution in a proper condition for biosensor analysis, by use of various buffer agents, adsorbents, and/or catalysts, depending on the types of sample solutions or the biosensor involved. For example, the control means may contain catalysts which are capable of converting interfering substances such as vitamin B_2, vitamin C, tannic acid, or anthocyanin into "harmless" substances which the biosensor is less likely to erroneously detect as an analyte. The control means may also contain an adsorbent material that

may function to adsorb and remove any interfering substances, or it may contain a buffering agent, which can act to adjust the pH to a level at which the enzyme contained in the biosensor may function more efficiently.

As is described in the Background section of the specification and in some of the prior art of record, conventional practice for detection of an analyte may utilize a biosensor having a component, integral to, or in close proximity with, the biosensor electrode, which contains an additional means intended to act to remove or neutralize any interfering substances in order to place the solution in a better condition for the detection reaction. This additional means does not function in the detection reaction, which is the primary activity of the biosensor, but is complementary to such activity.

Detection processes using a biosensor configured in this manner suffer from several drawbacks. For example, because the biosensor and the additional means are exposed to the sample solution almost simultaneously, the conditioning of the sample solution is not necessarily completed before the analyte detection reaction is accomplished. Thus, the measurement obtained may still be substantially affected by interfering substances. Additionally, use of biosensors containing a conditioning means integral to, or in close proximity with, the biosensor electrode does not permit use of the same biosensor with different sample solutions, if such solutions contain disparate interfering substances having differing chemical behaviors, and which therefore may not necessarily be efficiently eliminated or reduced in the same manner.

The Examiner has maintained his anticipation rejection based upon four previously cited prior art references and one new prior art reference, asserting that each individually anticipates one or more claims of the present invention.

Heller discloses a biosensor having an electrode substantially covered by a "sensing layer," and, on top of the sensing layer, an interferant eliminating layer, consisting of a catalyst which is capable of oxidizing, and thereby eliminating, interfering substances, and a third outer "oxidant generating layer." *See, e.g.,* Figure 3. The Heller layered electrode may be placed in a cell to which a sample solution is added, or it may be inserted into a sample solution.

Foulds discloses a dry strip element to be used in an electrochemical assay method for detecting theophylline in human biological fluids. The element is made up of a working electrode and a reference electrode. At the working electrode is an alkaline phosphatase and an electroinactive phosphate ester. The dry strip element may also incorporate a buffer having a pH of 9 to 10, and the buffer is positioned between the region of the sample application

and the alkaline phosphatase. Foulds teaches that one may incorporate into the test element isoenzymes to remove any alkaline phosphatase indigenous to the sample, which may reduce the desired substrate prior to the detection reaction, but will not interfere with the detection reaction itself.

Nankai discloses an improved enzyme electrode which is made up of a first electrode having one or more enzymes immobilized upon it and a second electrode which functions to remove materials which may interfere with the detection to be carried out by the first electrode. To accomplish electrochemical detection using this electrode, both the first and the second electrode are submerged in the test solution. The second electrode serves to electrochemically oxidize any interfering substances as the detection is accomplished by the first electrode.

Bockowski discloses a sensor electrode utilized in the presence of one or more filters made of such materials as adsorbents, such as activated carbon. The sensor electrode and the filters are located within close proximity to one another and are contained together in an electrode support housing.

A reference cannot anticipate an invention unless it teaches or discloses each and every element of the claimed invention. The prior art references cited by the examiner as the basis of his § 102(b) rejections describe electrochemical biosensors for use in the detection of various substances, or an apparatus for measurement of sulfuric acid from atmospheric air. None of the references teaches the specific control means of the present invention for converting a sample solution to a condition for analysis using a biosensor, wherein the biosensor and the control means are separate. The interferant reducing means in the cited prior art are physically or chemically coupled with the detection portion of the biosensor, not, as in the present invention, distinct from the biosensor. The interferant eliminating layer of Heller is sandwiched in between the reactive layers on the surface of the biosensing electrode. The isoenzymes of Foulds are incorporated into the test element of the dry strip. The oxidizing electrode of Nankai is proximate to the detection electrode, and performs its oxidation function almost simultaneously with the detection process of the other electode. The filters of Bockowski are located adjacent to the sensor electrode and are contained in close proximity in an electrode support housing.

Barden, art newly cited by the Examiner, discloses an apparatus for determining the level of sulfuric acid in the atmospheric air containing sulfur dioxide and ammonium sulfates. The apparatus comprises a transport chamber, collection chamber, a source of dilute

hydrochloric acid vapor, a pump means, a source of clean carrier gas, a detector means, and a cyclically operating time clock and valve means. The Barden reference does not teach a control means for converting a sample solution into a condition for detection using a biosensor, nor does it teach an instrument where a biosensor is separate from the control means. Contrary to the prior art, the present invention requires that the control means to be separate from the biosensor apparatus. The sample is properly adjusted within this separate control means, thereby better insuring an accurate measurement by the biosensor.

In light of the foregoing, it is respectfully requested that the Examiner reconsider and withdraw his § 102(b) rejections, and refrain from applying such rejections to the new claims.

CONCLUSION

For the reasons discussed above, it is submitted that the claims are fully compliant with 35 U.S.C. § 112 and patentably distinguish over all art of record and known to applicants. Accordingly, reconsideration and allowance of the claims are earnestly solicited.

Respectfully submitted,

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DATE

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MARKED-UP VERSION OF ABSTRACT OF DISCLOSURE

[The present invention provides a] A sample solution treating instrument is provided for facilitating rapid and simplified adjustment of the condition of a sample solution proper for analysis with a biosensor before [supply] supplying the solution to the biosensor. The sample solution treating instrument [in accordance with the present invention comprises control means, such as a] includes, for example, a catalyst or an adsorbent [,for example,] which can remove any interfering substance [for adjusting] in order to adjust the sample solution [proper] for measurement with a biosensor.